UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

GREGORY A. AMOS, in his capacity as Administrator of the Estate of ANDREA R. AMOS, Deceased,

Plaintiff,

13-CV-6375T

v.

DECISION and ORDER

BIOGEN IDEC INC. and ELAN PHARMACEUTICALS, INC.,

Defendants.

INTRODUCTION

Plaintiff Gregory A. Amos, the widower of Andrea R. Amos ("Amos") and administrator of her estate, brings this wrongful death action against defendants Biogen Idec Inc., ("Biogen") and Elan Pharmaceuticals, Inc. ("Elan") claiming that Andrea Amos died as the direct result of taking the prescription drug Tysabri, which was developed, marketed, and sold by the defendants. Specifically, plaintiff claims that Amos's use of the drug Tysabri caused her to develop a fatal infection in her brain.

Plaintiff's Complaint alleges nine separate causes of action against the defendants, including claims for negligence, strict products liability, design defect, failure to warn, negligent misrepresentation, fraud, breach of implied warranty, violation of the New York State General Business Law, and wrongful death.

The defendants deny plaintiff's allegations, and move to dismiss five of the claims asserted by the plaintiff. Specifically, defendants move to dismiss plaintiff's claims of

strict liability, design defect, negligent misrepresentation, fraud, and violation of the New York Business Law.

For the reasons set forth below, I grant defendants' motion to dismiss plaintiff's design defect claims, and New York General Business Law claim with prejudice. I grant defendants' motion to dismiss plaintiff's fraud claim without prejudice, and deny defendants' motion to dismiss plaintiff's strict liability claim based on failure to warn, and plaintiff's claim for negligent misrepresentation.

BACKGROUND

In 2005, Andrea Amos, the wife of plaintiff Gregory Amos, was diagnosed with the disease Multiple Sclerosis ("MS"). In September, 2006, plaintiff began taking the prescription drug Tysabri to treat the symptoms of her disease. According to the Complaint, Tysabri is a "potent immunosuppressant drug" that attempts to relieve MS symptoms by inhibiting inflamation that causes damage to the myelin sheath of MS patients. Tysabri is manufactured and sold by two independent drug manufacturers, Biogen Idec Inc., and Elan Pharmaceuticals, working under a joint collaboration agreement.

According to the Complaint, because Tysabri is such a strong immunosuppressant drug, it weakens the immune system of patients taking the drug, leaving those patients vulnerable to infections that would not ordinarily harm a person with a fully-functioning immune system. Plaintiff claims that Tysabri has been shown to cause a specific, deadly infection known as Progressive Multifocal

Leukoencephalopathy ("PML"), that occurs when a normally benign virus, the JC virus, that typically lays dormant in the human kidney, migrates to the human brain because the body's compromised immune system is incapable of containing the virus. According to the Complaint, once the JC virus enters the brain, it rapidly replicates, often resulting in impaired cognition, cortical blindness, and weakness on one side of the body. Plaintiff claims that PML usually causes death within one to four months of the onset of the disease.

Plaintiff took the drug Tysabri from approximately September, 2006 to sometime in mid 2011. In May, 2011, Amos began to experience difficulty understanding and communicating with people. She also experienced double vision and mobility difficulties. In August, 2011, Amos was diagnosed with PML, and according to her death certificate, on September 20, 2011, her death was caused by the disease.

In 2013, plaintiff brought the instant action against the defendants alleging, inter alia, that the defendants failed to warn physicians and patients of the significant dangers of taking Tysabri. Plaintiff claims that despite the fact that the defendants knew, or should have known, that long-term use of the drug greatly increased the risk of contracting PML, the defendants failed to warn doctors and patients of that consequence, and indeed, suggested that there was no correlation between long-term use of the drug and increased risk of PML. Plaintiff also alleges that the defendant knew, or should have known, that patients using

Tysabri were more likely to develop PML if they had previously been taking an immunosuppressant drug, and failed to warn doctors and patients of such an increased risk. The defendants' deny plaintiff's allegations, and move to dismiss five of the nine causes of action srt forth in plaintiff's Complaint.

DISCUSSION

I. Standard for Motion to Dismiss

In reviewing a motion to dismiss pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, the Court must "accept...all factual allegations in the complaint and draw...all reasonable inferences in the plaintiff's favor." See Ruotolo v. City of New York, 514 F.3d 184, 188 (2d Cir.2008) (internal quotation marks omitted). In order to withstand dismissal, the complaint must plead "enough facts to state a claim to relief that is plausible on its face." See Bell Atl. Corp. v. Twombly, 550 U.S. 544, 127 S.Ct. 1955, 1974 (2007) (disavowing the oft-quoted statement from Conley v. Gibson, 355 U.S. 41 (1957), that "a complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief").

"While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." See id. at 1965 (internal quotation marks omitted). Moreover,

conclusory allegations are not entitled to any assumption of truth, and therefore, will not support a finding that the plaintiff has stated a valid claim. Hayden v. Patterson, 594 F.3d 150, 161 (2d Cir., 2010). Thus, "at a bare minimum, the operative standard requires the 'plaintiff [to] provide the grounds upon which his claim rests through factual allegations sufficient to raise a right to relief above the speculative level.'" See Goldstein v. Pataki, 516 F.3d 50, 56-57 (2d Cir., 2008) (quoting Twombly, 127 S.Ct. at 1974).

Defendants move to dismiss five causes of action asserted by the plaintiff. Defendants move to dismiss plaintiff's claims for design defect (set forth in Counts Two and Three of the Complaint) on grounds that those claims are preempted by federal law. Defendants move to dismiss plaintiff's claim of strict liability for failure to warn (set forth in Count Two of the Complaint) on grounds that plaintiff has failed to properly allege such a cause of action. Defendants move to dismiss plaintiff's claims of negligent misrepresentation and fraud (set forth in Counts Five and Six of the Complaint respectively), on grounds that plaintiff has failed to state those claims with particularity as required by Rule 9(b) of the Federal Rules of Civil Procedure ("Rule 9(b)"). Finally, defendants claim that plaintiff's cause of action under the New York State General Business Law (set forth in Count Eight of the Complaint) fails to state a claim because the plaintiff has failed to establish that the defendants engaged in a "consumer oriented" trade practice as required under that law.

II. Design Defect

Plaintiff claims that Tysabri was not reasonably safe for its intended use, and therefore, was defectively designed. Plaintiff alleges two separate causes of action based on the alleged defective design of Tysabri, one sounding in strict liability, and the other sounding in negligence.

Under New York law, claims of design defect sounding in negligence are "functionally synonymous" to claims for design defect sounding in strict liability, and as a result, the claims are analyzed identically. Cavanagh v. Ford Motor Co., 13-CV-4584, 2014 WL 2048571 (E.D.N.Y. May 19, 2014). In the instant case, defendants move to dismiss plaintiff's design defect claims on grounds that such claims are preempted by federal law. In support of their argument, defendants cite the recent United States Supreme Court case of Mutual Pharmaceutical Co., Inc. v. Bartlett, which held that state-law causes of action for the alleged defective design of a drug regulated and approved by the FDA were preempted by federal law. Specifically, the Court held that because a drug manufacturer could not simultaneously comply with FDA requirements mandating the specific design of an approved drug and state law requirements mandating that the design be altered, the state-law requirements were preempted by federal law. Mutual Pharmaceutical Co., Inc. v. Bartlett, 570 U.S. _____ , 133 S.Ct. 2466, 2477(2013)("Because it is impossible for [plaintiff] and other similarly situated manufacturers to comply with both state and federal law, [the state's] warning-based design-defect cause of

action is pre-empted with respect to FDA-approved drugs sold in interstate commerce. Mutual. Pharmaceutical. Co., Inc., 133 S. Ct. at 2477.

The plaintiffs concede that design defect claims are preempted under federal law, and have agreed to withdraw those claims without prejudice. Because, however, such claims are preempted as a matter of law, I grant defendants' motion to dismiss plaintiff's claims of design defect set forth in Counts II and III of the Complaint with prejudice.

III. Strict Liability

In Count Two of the Complaint, plaintiff alleges that the defendants failed to adequately warn Amos of the risks of taking Tysabri, and are therefore strictly liable for the injuries she suffered as a result of taking Tysabri. Under New York law, a plaintiff may assert a claim for strict products liability on grounds that a product is "defective because of a mistake in the manufacturing process . . . or because of an improper design . . . or because the manufacturer failed to provide adequate warnings regarding the use of the product. Voss v. Black & Decker Mfg. Co., 59 N.Y.2d 102, 106-07 (1983). To state a prima facie case of liability on the basis of a defendant's failure to warn, the plaintiff must establish that "(1) the manufacturer had a duty to warn; (2) the manufacturer breached the duty to warn in a manner that rendered the product defective, *i.e.*, reasonably certain to be dangerous; (3) the defect was the proximate cause of the plaintiff's injury; and (4) the plaintiff suffered loss or damage."

Bee v. Novartis Pharm. Corp., 12-CV-1421, 2014 WL 1855632 (E.D.N.Y. May 9, 2014) (citing McCarthy v. Olin Corp., 119 F.3d 148, 156 (2d Cir.1997).

Defendants move to dismiss plaintiff's strict liability claim alleging failure to warn on grounds that he has failed to sufficiently allege facts supporting such a claim. Although the defendants have moved to dismiss plaintiff's cause of action for strict liability based on defendants' alleged failure to warn, the defendants have not sought dismissal of plaintiff's cause of action for negligent failure to warn as set forth in Count Four of the Complaint. Under New York law, however, the elements of a cause of action for failure to warn based on strict liability or negligence are identical. Bee, 2014 WL 1855632 at *10 ("The[] prima facie elements of a failure to warn claim remain the same under New York law regardless of whether they sound in negligence or strict liability"). Accordingly, by failing to seek dismissal of plaintiff's claim for negligent failure to warn, defendants have implicitly conceded that plaintiff has sufficiently alleged a cause of action for negligent failure to warn. If, indeed plaintiff has sufficiently alleged a cause of action for negligent failure to warn, he will have also stated a cause of action for strict liability based on a failure to warn.

Regardless of the defendants' inconsistent position with respect to plaintiff's allegations of defendants failure to warn, I find that plaintiff has stated a plausible claim for strict liability based on the defendants' alleged failure to warn.

Plaintiff has satisfactorily alleged that the defendants had a duty to warn of potential dangerous risks of taking Tysabri. Plaintiff has further alleged that by failing to warn both doctors and consumers that the risk of contracting PML increased the longer a patient had been taking Tysabri, or that patients who had previously taken immunosuppressant drugs were at a higher risk for developing PML once they started taking Tysabri, the defendants rendered Tysabri to be dangerous to consumers. See Complaint at ¶ 34, 47. Plaintiff has additionally alleged that because Amos was unaware of risks that should have been disclosed to her, she continued to take Tysabri, and died as a result of taking the drug. Such allegations state a claim for liability based on a failure to warn. Accordingly, I deny defendant's motion to dismiss that portion of Count Two of the Complaint alleging that defendants are liable to the plaintiff for their alleged failure to warn of the dangerous consequences of taking Tysabri.

IV. Negligent Misrepresentation

Plaintiff alleges that the defendants failed to disclose information they knew of, or reasonably should have known of, concerning the dangers of taking Tysabri, and as a result, misrepresented the risks of using the drug, all of which resulted in harm to Amos. Defendants move to dismiss this claim on grounds that plaintiff has failed to plead this cause of action with particularity as required by Rule 9(b) of the Federal Rules of Civil Procedure.

I find, however, that plaintiff has sufficiently stated a claim for negligent misrepresentation. To state a claim for negligent misrepresentation under New York law, a plaintiff must allege that "(1) the parties stood in some special relationship imposing a duty of care on the defendant to render accurate information, (2) the defendant negligently provided incorrect information, and (3) the plaintiff reasonably relied upon the information given." LBBW Luxemburg S.A. v. Wells Fargo Sec. LLC, 12 CIV. 7311, 2014 WL 1303133 at *17 (S.D.N.Y. Mar. 31, 2014)(quoting Saltz v. First Frontier, LP, 782 F.Supp.2d 61, 82 (S.D.N.Y., 2010) (internal citations omitted), aff'd, 485 Fed.Appx. 461 (2d Cir. 2012).

Here, the plaintiff has alleged that Amos, as a user of Tysabri, stood in a "special relationship" with the defendants, the manufacturers and distributors of the drug. In determining whether or not parties stand in a "special relationship," courts consider three factors: "whether the person making the representation held or appeared to hold unique or special expertise; whether a special relationship of trust or confidence existed between the parties; and whether the speaker was aware of the use to which the information would be put and supplied it for that purpose." Suez Equity Investors, L.P. v. Toronto-Dominion Bank, 250 F.3d 87, 103 (2d Cir.2001); Williamson v. Stryker Corp., 12 CIV. 7083, 2013 WL 3833081 (S.D.N.Y. July 23, 2013). In this case, plaintiff has sufficiently alleged that the defendants held a unique and special expertise with respect to the drug Tysabri, that Amos, as a user of

Tysabri, had a special relationship of trust with the defendants, and that the defendants were aware that their public statements regarding the risks and dangers of Tysabri would be relied on by users of the drug. See e.g. Hughes v. Ester C Co., 930 F. Supp. 2d 439, 475 (E.D.N.Y. 2013)(vitamin manufacturer held special relationship with vitamin consumers where manufacturer portrayed itself as holding special expertise with regard to the purported health benefits of vitamins it sold).

Plaintiff has also sufficiently alleged that the defendants negligently provided incorrect information about the drug. For example, the plaintiff has alleged that although the defendants knew or should have known that using Tysabri on a long term basis could increase the risk of contracting PML, the defendants failed to disclose such information to Amos, and in fact, alleged there was no correlation between long-term use of Tysabri and increased risk of developing PML. Complaint at ¶ 34. Finally, plaintiff has alleged that Amos relied, to her detriment, on the misrepresentations made by the defendants.

The defendants contend that plaintiff has failed to plead this cause of action with particularity, and therefore, the claim must be dismissed under Rule 9(b) of the Federal Rules of Civil Procedure. Rule 9(b) provides that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake" Fed. R. Civ. P. 9(b). Although many district courts in the Second Circuit have held that Rule 9(b) applies to claims of negligent misrepresentation asserted under New

York law, the Second Circuit Court has explicitly declined to make such a finding. As stated by the court in Eternity Global Master Fund Ltd. v. Morgan Guar. Trust Co. of N.Y. 375 F.3d 168, 188 (2d Cir. 2004), "Rule 9(b) may or may not apply to a state law claim for negligent misrepresentation. District court decisions in this Circuit have held that the Rule is applicable to such claims . . . . but this Court has not adopted that view . . . ." Here, I find that plaintiff's claims are not subject to the particularity requirements of Rule 9(b).

Among the nine causes of action set forth in the Complaint, plaintiff has alleged distinct causes of action for fraud and negligent misrepresentation. There is no question that plaintiff's cause of action for fraud is subject to the particularity requirements of Rule 9(b). Plaintiff's negligent misrepresentation claim, however, does not rely on a showing of fraud or mistake, and accordingly, it would be improper to impose the heightened pleading standard for fraud claims where fraud is not an element of the claim being alleged. See In re Rezulin Products Liab. Litig., 133 F. Supp. 2d 272, 285 (S.D.N.Y. 2001)("allegations of intent to defraud or deliberate wrongdoing are not essential" to a claim of negligent misrepresentation, and therefore "Rule 9(b) is not necessarily applicable to such claims.") Because plaintiff's negligent misrepresentation claim does not rely on proof of fraud, I decline to impose a heightened pleading standard on plaintiff's claim of negligent misrepresentation, and deny defendant's motion to dismiss that claim.

V. Fraud

Plaintiff alleges that the defendants fraudulently concealed information regarding the dangers of Tysabri, and knowingly misrepresented to the public that Tysabri was safe for its intended use. Defendants move to dismiss this claim on grounds that plaintiff has failed to plead his claims of fraud with particularity, as required by Rule 9(b). I find that plaintiff has failed to state his claims of fraud with particularity, and accordingly, I grant defendant's motion to dismiss without prejudice.

As stated above, Rule 9(b) requires that claims of fraud be pled with particularity. To satisfy this requirement, the Second Circuit has held that a complaint must (1) adequately specify the statements that plaintiff claims were false and misleading; (2) give particulars as to the manner in which plaintiff contends the statements were fraudulent; (3) state when and where the statements were made; and, (4) identify those responsible for the statements. Cosmas v. Hassett, 886 F.2d 8, 11 (2d Cir. 1989).

In the instant case, plaintiff has made only general allegations of fraudulent conduct, and the majority of plaintiff's averments regarding the alleged fraud are made only upon "information and belief." Typically, allegations of fraud that rest on claims made upon "information and belief" will fail to satisfy Rule 9(b)'s requirement of particularity. DiVittorio v. Equidyne Extractive Indus., Inc., 822 F.2d 1242, 1247 (2d Cir. 1987)("Rule 9(b) pleadings cannot be based upon information and

belief."). However, where the relevant facts "'are peculiarly within the opposing party's knowledge,' and the plaintiff has no access to those facts", courts will not require unflagging adherence to Rule 9(b)'s particularity requirement. U.S. ex rel. Kester v. Novartis Pharm. Corp., 11 CIV. 8196 CM, 2014 WL 2619014 at *6 (S.D.N.Y. June 10, 2014) (quoting Boykin v. Keycorp, 521 F.3d 202, 215 (2d Cir.2008). Nevertheless, a plaintiff alleging fraud must still provide detailed allegations of the alleged fraud, and cannot rely on conclusory or speculative allegations.

In the instant case, I find that plaintiff's allegations of fraud have not been alleged with sufficient particularity. For example, although plaintiff alleges that the defendants paid ghostwriters to author articles favorable to the use of Tysabri, no such article is identified. Similarly, although the plaintiff alleges that the defendants knew of and suppressed information regarding 12 suspected cases of PML linked to Tysabri, that allegation is made only on information and belief, and no further details are alleged. Plaintiff further claims that defendants made misrepresentations in advertisements, website statements, written and oral information provided to patients and doctors and other marketing materials, but fails to identify any such misrepresentation, and fails to explain why such misrepresentations were fraudulent. These general averments of fraud lack the particularity required by Rule 9(b), and therefore, I grant defendants' motion to dismiss plaintiff's fraud claims.

Complaints dismissed under Rule 9(b), however "are 'almost always' dismissed with leave to amend." Luce v. Edelstein, 802 F.2d 49 (2nd Cir. 1986)(citing 2A J. Moore & J. Lucas, Moore's Federal Practice, ¶ 9.03 at 9-34 (2nd ed. 1986)); Apace Communications, Ltd. v. Burke, 522 F.Supp.2d 509, 523 (W.D.N.Y.2007) (Larimer, D.J.) ("dismissal under Rule 9(b) is usually without prejudice") (quoting In re Time Warner Inc. Securities Litigation, 9 F.3d 259 (2d Cir.1993)); Ozbakir v. Scotti, 764 F. Supp. 2d 556, 574 (W.D.N.Y. 2011). Accordingly, defendants' motion to dismiss plaintiff's fraud claim is dismissed without prejudice.

VI. New York General Business Law Section 349

Section 349 of the New York General Business Law provides generally that it is unlawful to engage in any deceptive act or practice with respect to the transaction of business in New York State. N.Y. Gen Bus. L § 349(a). To state a claim for deceptive trade practices under this section, a plaintiff must establish that: (1) the defendant engaged in an act that was directed at consumers; (2) the act engaged in was materially deceptive or misleading; and (3) the plaintiff was injured as a result of the defendant's act. Oswego Laborers Local 214 Pension Fund v. Marine Midland Bank N.A., 85 N.Y.2d 20, 25 (1995); Stutman v. Chem. Bank, 95 N.Y.2d 24, 29, 709 N.Y.S.2d 892, 731 N.E.2d 608 (2000).

In the instant case, plaintiff alleges that the defendants deceived consumers by concealing information about the dangers of taking Tysabri, and that Amos died as a result of the defendants

deceptive practices. I find, however, that because a drug manufacturer's duty to warn of a drug's side effects runs to the doctor prescribing the drug, and not to the user of the drug, the issuance of drug warnings, for purposes of Section 349, is not an act directed at consumers, and therefore any alleged deceptive act related to the issuance of those warnings is not a "consumer oriented" act actionable under Section 349 of the New York General Business Law.

It is uncontroverted that Section 349 of the New York General Business Law prohibits deceptive practices that are directed to consumers. "[A]s a threshold matter, plaintiffs claiming the benefit of section 349 . . . must charge conduct of the defendant that is consumer-oriented." Oswego Laborers' Local 214 Pension Fund, 85 N.Y.2d at 25. It is further uncontroverted that under New York law, drug manufactures do not owe consumers a duty to warn of a drug's risks, but instead owe such a duty to the prescribers of that drug. Bee v. Novartis Pharm. Corp., 12-CV-1421, 2014 WL 1855632 at *11 (E.D.N.Y. May 9, 2014)("In the prescription drug context, courts have recognized that a manufacturer's duty to warn extends to a patient's doctor (and not to the patient himself) . . . ."). This is because unlike other consumer products that may be freely purchased by consumers, prescription drugs may only be purchased by pursuant to a prescription issued by a medical doctor. Thus, New York state has adopted the "informed intermediary doctrine," which provides that the duty to warn of a drugs side effects and risks runs to the doctor prescribing the drug, and not

to patient taking the drug. Lindsay v. Ortho Pharm. Corp., 637 F.2d 87, 91 (2d Cir. 1980)("Except where FDA regulations otherwise provide, the manufacturer's duty is to warn the doctor, not the patient."). Accordingly, because the defendants' alleged deceptive practice of failing to provide adequate warnings by concealing information is not, as a matter of law, a practice directed at consumers, plaintiff has failed to allege a consumer-oriented practice cognizable under Section 349 of the New York General Business Law. Such a finding, of course, does not preclude the plaintiff from proceeding with his claim that defendants failed to adequately warn Amos' doctors of the risks of taking Tysabri and are therefore strictly liable, or liable as a result of negligence, for their alleged failure to warn.

CONCLUSION

For the reasons set forth above, I grant defendants' motion to dismiss plaintiff's design defect claims, and New York General Business Law Claim with prejudice. I grant defendants' motion to dismiss plaintiff's fraud claim without prejudice, and deny defendants' motion to dismiss plaintiffs strict liability claim based on failure to warn, and claim for negligent misrepresentation.

ALL OF THE ABOVE IS SO ORDERED.

S/Michael A. Telesca

MICHAEL A. TELESCA
United States District Judge

Dated: Rochester, New York
June 25, 2014